510(K) SUMMARY

OCT 20 2010

A. Submitter Information

DePuy Spine, Inc.
325 Paramount Drive
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Regulatory Affairs Project Manager
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B. Date Prepared 9/17/2010

C. Device Name

Trade/Proprietary Name: Viper Spine System

Common/Usual Name: Spinal System

Classification Name: Spinal interlaminar fixation orthosis
per 21 CFR §888.3050
Spinal intervertebral body fixation orthosis
per 21 CFR §888.3060
Pedicle screw spinal fixation
per 21 CFR §888.3070

D. Predicate Device Name

Trade name: DePuy Spine VIPER® Spine System (K090648)
DePuy Spine EXPEDIUM® System (K041119, K033901, K090230, K071495)
DePuy Spine Moss Miami® System (K011182, K953915)

E. Device Description

The VIPER® Systems consist of rods and cannulated screws used in a percutaneous approach and are available in various geometries and sizes. The proposed Viper® 4.35mm diameter cannulated screws maintain the identical cannulation through the center of the screw shank as the previously cleared Viper® pedicle screws. The screw shank component of the proposed screws will have the same dual lead thread form, tapered distal tip, and same flutes as the previously cleared Viper® screws and are available in polyaxial or uniplanar configurations.

F. Intended Use

The VIPER® System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The VIPER® System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a percutaneous approach with MIS Instrumentation, the VIPER® Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed modifications to the DePuy Viper® Spinal System are identical to the predicate device with one minor difference. The only change is the inclusion of polyaxial and uniplanar pedicle screws of differing diameters that were not originally cleared in the predicate 510k. The design, materials, and technology remain identical to the predicate system.

G. Materials

Manufactured from ASTM F 138 implant grade stainless steel and ASTM F 136 implant grade titanium alloy.

H. Performance Data

Performance data per ASTM F 1717 were submitted to characterize the subject VIPER System components addressed in this notification. This testing was compromised of static and fatigue testing on the proposed device. Specifically, static and dynamic compression testing as well as static torsion and cantilever beam testing were performed.

I. Conclusion

Both the Performance Testing and Substantial Equivalence Justification demonstrate that the device is as safe, as effective, and performs as well as the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 20 2010

DePuy Spine, Inc.
% Mr. Kevin G. Stevens
Regulatory Affairs Project Manager
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K102701
Trade/Device Name: Viper™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: September 17, 2010
Received: September 20, 2010

Dear Mr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102701

Device Name: Viper™ Spinal System

OCT 20 2010

Indications For Use:

The VIPER System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The VIPER System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a percutaneous approach with MIS Instrumentation, the VIPER Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102701